Gastrointestinal tumours

Updated analysis: Phase II trial of irinotecan plus S-1 (IRIS) with cetuximab (IRIS/Cet) in pre-treated patients with KRAS wild type metastatic colorectal cancer (mCRC): HGCSG0902


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Aim/Background: FIRIS trial reported that IRIS demonstrated the non-inferiority to FOLFIRI as second-line treatment in patients with KRAS wild type mCRC (20050181 trial). Thus we conduct this study (HGCSG0902) to evaluate safety and efficacy combined IRIS and cetuximab (IRIS/Cet).

Methods: HGCSG0902 is a multicenter phase II study. Eligibility includes histologically confirmed colorectal cancer, previously received oxaliplatin-contained chemotherapy, PS: 0-1 and KRAS exon2 wild type. Patients received S-1 80-120 mg/day p.o. on days 1-14 and irinotecan 100mg/m2 on days 1 and 15 repeated every 28 days. Cetuximab was administrated 400mg/m2 loading dose and continued 250mg/m2 every week or 500mg/m2 bi-weekly. The primary endpoint was response rate and the secondary endpoints were disease control rate, PFS, OS and safety. We estimated that a target sample size of 76 patients.

Results: Between Mar 2010 and September 2013, 58 pts were enrolled. One patient was not administered (57 pts were safety analysis set), and 3 pts were ineligible (54 pts were efficacy analysis set). Patients characteristics were as follows: median age 66 years (range 35-79), male: female 36:21, PS 0:1 38:19. Median number of cycles was 3. The main grade 3-4 AE were diarrhea (35.1%), neutropenia (26.8%), acne like rash (17.5%) and anorexia (15.8%). Response rate was 33.3% (95%CI 20.8-45.9%) and disease control rate was 79.6%. Median progression-free survival was 4.7 months (95%CI 3.3-6.1 months) and median survival time was 10.1 months (95%CI 7.8-12.4 months).

Conclusions: IRIS/Cet appeared to be highly effective with response rate of 33.3%, progression-free survival of 4.7 months, overall survival of 10.1 months, and had met the primary endpoint. Diarrhea as one of major adverse events could be manageable by appropriate dose reduction and supportive care. However, further control of diarrhea will be required for the future development of IRIS/Cet. This analysis had been presented at the European Cancer Congress 2015 (Nakamura M, et al. Abstract number was 2 096).


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